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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,741	10/06/2000	IB Mendel-Hartvig	10806-128	1595

7590 08/09/2004

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Cincinnati, OH 45202

EXAMINER

COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 08/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/582,741

Applicant(s)

MENDEL-HARTVIG ET AL.

Examiner

Gary W. Counts

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 12 July 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 07/12/04. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 1-4, 6 and 11-39.

Claim(s) withdrawn from consideration: _____

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____

DETAILED ACTION**Attachment to Advisory Action**

Continuation of 5 NOTE: Applicant argues that Rylatt et al fails to teach all of the detection zones (DZ) downstream of all of the calibrator zones (CZ) in the lateral flow matrix and that Rylatt teaches test zone 204 arranged between calibration zones 210 and 211. This is not found persuasive because of reasons stated in the previous office action and further because Examiner has interpreted the claims to require only one calibration zone (i.e. claim 1, step (iii) (C) and claim 20, step (iii) one or more calibrator zones comprising a calibrator, or binder for the calibrator, which is firmly anchored to the matrix). Therefore the claim only requires one calibrator zone. Thus, Examiner has interpreted the claim to read as one calibrator zone comprising a calibrator, or binder for the calibrator, which is firmly anchored to the matrix. This limitation is clearly taught by Rylatt et al. Rylatt et al teaches on calibration zone (210) and one detection zone (204) downstream of the one calibration zone. Therefore, since the claim only requires one calibration zone and one detection zone, Rylatt et al meets the limitations of claims 1 and 20 and therefore reads on the instantly recited claims. Applicant further state that if more than one calibrator zone is employed, all of the detection zones are downstream of all of the calibrator zones CZ in the lateral flow matrix and that Rylatt do not teach all of the detection zones down stream of all of the calibrator zones. This is not found persuasive because as stated above the claim only requires the use of one calibrator zone and one detection zone DZ downstream of the one calibrator zone (limitation taught by Rylatt).

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Applicant argues that Van Deusen et al provide no teaching or suggestion relating to a lateral flow method or device. This is not found persuasive because Rylatt et al teaches this limitation. Van Deusen teaches the advantages of labeled reagent, which binds to both the calibrator and the analyte. Applicant further argues that Van Deusen fails to teach improving reliable calibration in lateral flow techniques. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., improving reliable calibration in lateral flow techniques) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that only in hindsight would one of ordinary skill in the art be motivated to combine the teachings of Van Deusen et al with the lateral flow method and apparatus of Rylatt et al in order to obtain the advantage of avoiding process variations between testing and calibration which are avoided to the present methods. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from

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the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant further argues that neither Rylatt et al nor Van Deusen et al teach a lateral flow matrix method wherein a single analytical detectable reactant may be employed. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Rylatt et al clearly teaches a lateral flow device and method and Van Deusen et al specifically teaches the advantages of using a single analytical detectable reactant. Applicant also argues that neither Rylatt et al nor Van Deusen et al teach a lateral flow method or device employing a lateral flow matrix wherein all detection zones are downstream of all calibration zones. This is not found persuasive because of reasons stated in the previous office action and reasons stated above.

Applicant argues that Van Deusen et al teach a test strip for placement in a test solution and subsequent placement in a solution containing identifier and that Van Duesen et al provide no teachings or suggestions relating to lateral flow techniques. This is not found persuasive because Rylatt et al teaches lateral flow techniques as recited in the instant claims. Rylatt et al also teaches the use of labeled reagents. Van Deusen's teaching of the subsequent placement in a solution containing identifier is irrelevant because Examiner has relied upon Rylatt et al for teaching a test strip containing labeled reagents (identifiers) to the

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analyte and the calibrator. Van Deusen et al is relied upon for teaching a labeled reagent, which binds to both the calibrator and the analyte (col 4, lines 34-54).

Further, Van Deusen teaches the advantage that the use of a single label reagent provides for a standard area and a test area having both calibrator and analyte produced on the same test strip and provides for methods in which it is not necessary for the reactants to come to equilibrium. Further, one skilled in the art would recognize that by replacing the labeled reagents of Rylatt et al with the identifier (label reagent) of Van Deusen et al would provide a test strip utilizing one less reagent and therefore be more cost efficient. Therefore, it is Examiner's position that the combination of Rylatt et al and Van Deusen et al is proper and reads on the instantly recited claims.

Applicant argues that Rylatt et al and Van Deusen et al fail to teach or suggest the advantages taught in the present specification. This is not found persuasive because the combination of Rylatt et al and Van Deusen et al teaches all the structural limitations as recited in the instant claims and therefore would provide the same advantages as Applicant's invention. Further, Applicant has not provided any evidence that Applicant's invention works better ^{than} ~~that~~ the prior art.

Applicant argues that the tertiary references Self et al and Weng et al do not resolve the deficiencies of Rylatt et al and Van Deusen et al and thus the references have been overcome. This is not found persuasive because it is the Examiner's position that Rylatt et al and Van Deusen et al read on the instantly


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recited claims and therefore the combination of the tertiary references with Rylatt and Van Deusen is proper and reads on the instantly recited claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Gary Counts
Examiner
Art Unit 1641
August 4, 2004


CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641
8/6/04